K071666

Bio-Medical Research Ltd.

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This 510k summary is being submitted in accordance with the requirements of 21 CFR 807.92.

MAR 12 2008

1. Contact Details

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Prepared:	13h June, 2007, Revised 11h March 2008

2. Device Name

Trade Name of Device:	Slendertone EnerVive™, Type 561
Common Name:	Muscle Stimulator
Classification Name:	Stimulator, muscle, powered, for muscle conditioning (NGX)

3. Identification of Equivalent Legally Marketed Device

Name:	Compex Sport, Model Sport 3
Manufacturer:	Compex S.A.
510(k) Number:	K011880

4. Description of Device

EnerVive™ is the latest product offering from Slendertone, a division of Bio-Medical Research Ltd. It is a portable two-channel; battery operated neuromuscular electronic stimulation system. The device uses the principles of Neuromuscular Electrical Nerve Stimulation (NMES) and is intended for over the counter use by healthy adults for the stimulation of healthy muscles in order to improve or facilitate muscle performance. It is not intended as a therapy for any medical condition.

The two channels may be operated independently when each lead wire is attached to the unit and to the supplied butterfly-shaped electrode pads. Detailed diagrams for correct pad placement are available as part of the instructions for use.

EnerVive™ stimulates action potentials in the motor nerves supplying muscle. Different patterns of muscle activity can be imposed on the target muscle, depending on the timing and intensity of the stimulation signal. EnerVive™ contains 6 programs for exercise warm-up, muscle performance improvement and exercise recovery.

Included in the product pack are an ergonomically designed EnerVive™ control unit, 4 adhesive pads (2 pairs), 1 x 9 volt battery (6F22), a belt clip, 2 lead wires, travel pouch and instructions for use.

5. Statement of Intended Use/Indications for Use

Indications for use are the same as the listed predicate device. EnerVive™ is intended for use by healthy persons to apply transcutaneous electrical muscle stimulation (EMS) through skin contact electrodes. Indications for use are as follows:

"EnerVive™" is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

"EnerVive™" is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the "EnerVive™" training programs are designed for injured or ailing muscles and its use on such muscles is contraindicated.

The "EnerVive™" electrical impulses allow triggering action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

The various types of muscle work that "EnerVive™" can impose on the stimulated muscles are able to improve or facilitate muscle performance. "EnerVive™" may therefore be considered a technique of muscle training.

EnerVive™" is intended for over the counter sales.

6. Summary of Technological Characteristics

A summary of the technological characteristics of the EnerVive™ device compared to the predicate devices in terms of design, material and energy source is given below:

	EnerVive™	**Compex Sport**
Type/Model	561	Sport 3
Design	Stimulator unit, leads/cables (2), adhesive electrodes (4), user instructions & pouch. 2 channels	Stimulator unit, battery charger, leads/cables (4), adhesive electrodes, user instructions & case. 4 channels
Material	Unit Housing – ABS Plastic	Unit Housing - Plastic
Energy Source	1 x 9 volt battery	7.2 V NiMH rechargeable battery

Comparison in basic unit characteristics and output specifications for the device and the predicate have been compiled using the "Guidance Document for Powered Muscle Stimulator 510(k)s", June 1999 and have been submitted as part of this 510(k) Premarket Notification.

Slendertone EnerVive™ uses the same technology as the predicate device i.e. low frequency pulsed electrical stimulation, using constant-current controlled, symmetric biphasic pulses. Both products use almost identical timing parameters, and it is the frequency ranges of the applied pulses that determine the pattern of activity imposed on the muscle fibers.

7. Substantial Equivalence

Bio-Medical Research Ltd (BMR) has over 30 years experience in the research, design, manufacture and marketing of medical grade products for both muscle strengthening and pain relief. Bio-Medical Research Ltd. complies with 21 CFR 820 and is registered to I.S. EN ISO 13485:2003, Medical Device Quality Management System for the design, manufacture and distribution of electro-medical devices.

EnerVive™ complies with the following international safety standards:

- EN 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and Tests.
- EN 60601-1 (1990) + A1 (1993) + A2 (1995) +A13 (1996) + Corrigenda (July 1994) – Medical Electrical Equipment – Part 1: General Requirements for Safety
- IEC 60601-2-10, 1st ed., 1987 - Medical Electrical Equipment Part 2: Particular Requirements For The Safety Of Nerve And Muscle Stimulators.

A risk management plan has been carried out to I.S. EN ISO 14971 2001 AMD 1 2003.

As with the predicate device, the evidence for effectiveness of this technology in facilitating or improving the performance of skeletal muscle relies on the large body of research literature on EMS extending over several decades. The following research articles have been referenced for this 510(k) Premarket Notification.

1. Alon G. "Principles of Electrical Stimulation" in Nelson RM., Currier DP. " Clinical Electrotherapy", 2nd Ed, pp 35-103 Appleton and Lange 1991

2. Baker LL,Wederich CL,McNeal DR,Newsam C,Waters RL. "Neuromuscular Electrical Stimulation. A Practical Guide. 4th Ed. Rancho Los Amigos. 2000

3. Bax Leon, Staes Filip, Verhagen Arianne. "Does Neuromuscular Electrical Stimulation Strengthen the Quadriceps Femoris, A Systematic Review of Randomised Controlled Trials" Published Sports Med 2005:35(3):191-212 0112-1642/05/0003-0191/S34.95/0

4. Hainault Karl, Duchateau Jacques "Neuromuscular Electrical Stimulation and Voluntary Exercise" Published Sports Medicine 14(2):100-113.1992 0112-1642/92/0008-0100/$7.00/0

5. S. C. Small and M. J. Stokes, "Stimulation frequency and force potentiation in the human adductor pollicis muscle" *European Journal of Applied Physiology,* vol. 65, p. 5, 1992.

6. G. M. Lyons, G. E. Leane, and P. A. Grace, "The effect of electrical stimulation of the calf muscle and compression stocking on venous blood flow velocity," *Eur J Vasc Endovasc Surg,* vol. 23, pp. 564-6, Jun 2002.

7. J. E. Sherry, K. M. Oehrlein, K. S. Hegge, and B. J. Morgan, "Effect of burst-mode transcutaneous electrical nerve stimulation on peripheral vascular resistance," *Phys Ther,* vol. 81, pp. 1183-91, Jun 2001.

Further clinical data [8] was presented to detail the effectiveness of a dual electrode design in producing adequate muscle contractions. The dual electrode design, unlike that of the predicate, maintains a fixed distance between the electrodes. The study was performed in

compliance with Good Clinical Practices (GCP) and includes the archiving of essential documents.

8. Ciaran Byrne, MSc., Eta Tierney, "Quantitative Performance Measures of Slendertone Enervive," Bio-Medical Research Institute, Galway, Ireland.

Data was collected on 6 subjects who were representative of the intended use population. All participants provided informed consent prior to participation.

The study was conducted in compliance with the protocol, applicable FDA Regulations, applicable local Regulations, Good Clinical Practice Guidance, and the Declaration of Helsinki.

The results showed that effective muscle contractions were elicited when a group of healthy adults used EnerVive™. There were no adverse events during this study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bio-Medical Research Ltd.
% Ms. Anne-Marie Keenan
Parkmore Business Park West
Galway
Ireland

MAR 12 2008

Re: K071666
Trade/Device Name: Slendertone EnerVive™, Type 561
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: December 13, 2007
Received: December 17, 2007

Dear Ms. Keenan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: EnerVive™, Type 561

Indications for Use:

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The various types of muscle work that "*EnerVive*™" can impose on the stimulated muscles are able to improve or facilitate muscle performance. "*EnerVive*™" may therefore be considered a technique of muscle training.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ***X*** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071666